

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

RECRO GAINESVILLE LLC,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. _____
)	
ACTAVIS LABORATORIES FL, INC.,)	
)	
Defendant.)	

COMPLAINT

Plaintiff Recro Gainesville LLC (“Recro”), for its Complaint against Defendant Actavis Laboratories FL, Inc. (“Actavis”), alleges as follows:

PARTIES

1. Recro is a Massachusetts limited liability company having its principal place of business at 1300 Gould Dr., Gainesville, GA 30504.
2. Actavis is a Florida corporation having its principal place of business at 4955 Orange Dr., Davie, FL 33314.
3. On information and belief, Actavis is in the business of developing, manufacturing, marketing, importing, preparing, and selling generic pharmaceutical products and seeking regulatory approval under the Federal Food, Drug, and Cosmetic Act, including defending patent infringement litigations based on the filing of Abbreviated New Drug Applications (“ANDAs”). On information and belief, Actavis’s generic pharmaceutical products are distributed in the State of Delaware and throughout the United States.

NATURE OF ACTION

4. This is an action for infringement of United States Patent No. 9,713,611 (“the ’611 Patent”). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*

JURISDICTION AND VENUE

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b).

7. This Court has personal jurisdiction over Actavis because it has purposefully availed itself of the privilege of selling its pharmaceutical products in the State of Delaware and, therefore, can reasonably expect to be subject to jurisdiction in the Delaware courts. Among other things, on information and belief, Actavis conducts marketing and sales activities in the State of Delaware, including, but not limited to, the distribution, marketing, and sales of pharmaceutical products to Delaware residents that are continuous and systematic.

8. Actavis has previously submitted to the jurisdiction of this Court and has availed itself of this Court by initiating lawsuits, consenting to this Court’s jurisdiction, and asserting counterclaims in civil actions initiated in this jurisdiction. *See, e.g.,* Watson Labs., Inc.’s Answer, Affirmative Defenses, and Counterclaims at 4, *Forest Labs., Inc., et al. v. Apotex Corp. & Watson Labs., Inc. – Florida, et al.*, C.A. No. 14-200 (LPS) (D. Del. Apr. 22, 2014) (D.I. 22) (consenting to jurisdiction and venue and asserting counterclaims) and Notice of Name Change, C.A. No. 14-200 (LPS) (D. Del. June 6, 2014) (D.I. 48) (stating that Watson Laboratories, Inc. – Florida changed its name to Actavis Laboratories FL, Inc. on April 21, 2014); Stipulation and Order Dismissing Without Prejudice Defendants Andrx Corporation, Actavis Pharma, Inc., and

Actavis, Inc., and Amending Caption to Reflect Same, *Recro Gainesville LLC v. Actavis Labs. FL, Inc.*, C.A. No. 14-1118 (GMS) (D. Del. Sept. 23, 2014) (D.I. 11) (consenting to jurisdiction and venue) and Actavis Laboratories FL, Inc.’s Answer, Separate Defenses, and Counterclaims to Plaintiff’s Complaint, C.A. No. 14-1118 (GMS) (D. Del. Oct. 24, 2014) (D.I. 14) (consenting to jurisdiction and venue and asserting counterclaims); Actavis Laboratories FL, Inc.’s Answer, Separate Defenses, and Counterclaims to Plaintiff’s Complaint, *Recro Gainesville LLC v. Actavis Labs FL, Inc.*, C.A. No. 15-413-GMS (D. Del. June 16, 2015) (D.I. 6) (consenting to jurisdiction and venue and asserting counterclaims); Actavis Laboratories FL, Inc.’s Answer and Affirmative Defenses to Third Amended Complaint, *Pernix Ireland Pain Ltd. v. Actavis Labs. FL, Inc.*, C.A. No. 16-138-GMS (D. Del. Nov. 30, 2016) (D.I. 59) (consenting to jurisdiction and venue and asserting counterclaims); Actavis Laboratories FL, Inc.’s Answer, Affirmative Defenses, and Counterclaims, *Purdue Pharma L.P. v. Alvogen Pine Brook LLC & Actavis Laboratories FL, Inc.*, C.A. No. 15-687-GMS (consolidated) (D. Del. Oct. 20, 2017) (D.I. 253, 254, 255) (consenting to jurisdiction and venue and asserting counterclaims to complaints filed in C.A. Nos. 17-677-GMS, 17-1131-GMS, and 17-1369-GMS).

9. On information and belief, Actavis or its predecessor, Watson Laboratories FL, have appeared – and asserted counterclaims – in dozens of ANDA cases in the District of Delaware in the last decade.

10. On information and belief, Actavis Pharma Inc. distributes products developed and manufactured by Actavis Laboratories FL, Inc. On information and belief, Actavis Laboratories FL, Inc. and Actavis Pharma Inc. are related corporate entities that together perform the activities required to market bioequivalent generic versions of innovator drugs to consumers. On information and belief, Actavis Pharma Inc. is a Delaware corporation. On information and

belief, Actavis Pharma, Inc. has a registered agent in Delaware (located at The Corporation Trust Company, 1209 Orange Street, Wilmington, DE 19801) for the receipt of service of process.

FACTUAL BACKGROUND

11. On July 25, 2017, the '611 Patent, entitled "Abuse Resistant Pharmaceutical Compositions," was duly and legally issued to Recro. A true and correct copy of the '611 Patent is attached as Exhibit A.

12. On October 25, 2013, the United States Food and Drug Administration ("FDA") approved New Drug Application No. 202880 for Zohydro® ER extended-release capsules, which contain hydrocodone bitartrate, under § 505(a) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(a), for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. The '611 Patent is listed in Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for Zohydro® ER capsules.

13. On information and belief, Actavis submitted Abbreviated New Drug Application ("ANDA") No. 206952 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and sale of hydrocodone bitartrate extended-release capsules in the 10, 15, 20, 30, 40, and 50 mg strengths, as generic versions of the Zohydro® ER 10, 15, 20, 30, 40, and 50 mg capsules ("Proposed ANDA Products").

14. By letters dated August 12, 2014; April 6, 2015; and November 10, 2015, Actavis advised Recro that it had submitted ANDA No. 206952 to the FDA seeking approval to manufacture, use, or sell the Proposed ANDA Products prior to the expiration of Recro's U.S.

Patent Nos. 6,228,398 (the “’398 Patent”); 6,902,742 (the “’742 Patent”); and 9,132,096 (the “’096 Patent”), which are listed in the Orange Book for Zohydro® ER.

15. The ’611 Patent is a continuation of the ’096 Patent. The ’611 and ’096 Patents expire on the same day.

16. On information and belief, Actavis seeks to engage in the commercial manufacture, use, and sale of its Proposed ANDA Products before the expiration of the ’611 Patent.

17. Recro and its predecessors previously filed three actions in this Court asserting that Actavis’s submission of ANDA No. 206952 to the FDA seeking approval to manufacture, use, or sell its Proposed ANDA Products constitutes infringement of the ’398 Patent; the ’742 Patent; and the ’096 Patent. Those actions, filed on September 3, 2014 (C.A. No. 14-1118-GMS), May 21, 2015 (C.A. No. 15-413-GMS), and December 23, 2015 (C.A. No. 15-1196-GMS) were consolidated and proceeded to trial on October 3, 2016 (“Recro I”).¹

18. Recro I involved the same drug products as the present action. Recro I involved the infringement of the grandparent patent of the presently asserted ’611 Patent. Recro I and this case are expected to involve similar operative facts.

19. On February 22, 2017, the Court issued an opinion finding that Actavis’s Proposed ANDA Products infringe all asserted claims of the ’096 and ’742 Patents. On February 24, 2017, the Court entered an order enjoining the FDA from granting final approval to Actavis’s ANDA No. 206952 before the expiration of the ’096 and ’742 Patents, and enjoined Actavis and its “officers, agents, attorneys, and employees, and those acting in privity or concert with any of

¹ The parties stipulated before trial to the dismissal of all claims related to the ’398 Patent.

them” from making, using, selling, or offering to sell Actavis’s Proposed ANDA Products prior to the expiration of the ’096 and ’742 Patents.

20. Recro I is presently on appeal before the Federal Circuit.

21. On March 4, 2016, Pernix Ireland Pain Ltd. and Pernix Therapeutics, LLC (collectively, “Pernix”), brought suit in this district against Actavis for infringement of Pernix’s patents covering Zohydro® ER based on Actavis’s filing of ANDA No. 206952. *Pernix Ireland Pain Ltd. v. Actavis Labs. FL, Inc.*, C.A. No. 16-138-GMS (D. Del.) (the “Pernix Case”). The Pernix Case is scheduled for trial in April 2018.

22. On information and belief, Actavis continues to seek final approval of ANDA No. 206952 (and received tentative approval on August 26, 2016) prior to the expiration of the ’611 Patent, including by appealing the Court’s judgment in Recro I and contesting the Pernix Case.

COUNT I

23. Recro incorporates each of the preceding paragraphs 1 to 22 as if fully set forth herein.

24. Actavis’s submission of ANDA No. 206952 to the FDA for hydrocodone bitartrate extended-release capsules in the 10, 15, 20, 30, 40, and 50 mg strengths constitutes infringement of at least claim 1 of the ’611 Patent under 35 U.S.C. § 271(e)(2)(A). Actavis’s commercial manufacture, offer for sale, or sale of the proposed generic for hydrocodone bitartrate extended-release capsules in the 10, 15, 20, 30, 40, and 50 mg strengths would infringe at least claim 1 of the ’611 Patent.

25. On information and belief, Actavis is aware of the existence of the ’611 Patent and is aware that pursuing final approval of ANDA No. 206952 constitutes infringement of that patent. This is an exceptional case.

PRAYER FOR RELIEF

WHEREFORE, Recro respectfully requests the following relief:

- A. A judgment that Actavis has infringed the '611 Patent;
- B. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of ANDA No. 206952 for hydrocodone bitartrate extended-release capsules in the 10, 15, 20, 30, 40, and 50 mg strengths under § 505(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j), shall not be earlier than the expiration date of the '611 Patent, including any extensions;
- C. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Actavis, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from infringement of the '611 Patent for the full term thereof, including any extensions;
- D. A declaration that this is an exceptional case and an award of reasonable attorneys' fees pursuant to 35 U.S.C. § 285;
- E. Costs and expenses in this action; and
- F. Such other and further relief as the Court may deem just and proper.

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